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SECTION 5: 510(k) SUMMARY

Submitter: Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

OCT 2 2007

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Date of preparation: October 16, 2006

Name of device: **Trade/Proprietary Name:** Reprocessed Trocar
Classification Name: Laparoscope, General and Plastic Surgery

Predicate Device	510(k) Title	Manufacturer
K032676	ENDOPATH III Bladeless Trocars	Ethicon Endo-Surgery
	ENDOPATH III Blunt Tip Trocars	
	ENDOPATH III Dilating Tip Trocars	

*Applicable Trade Name/devices within K032676 to K070059 underlined.

Device description:

Trocars and cannulae are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery.

Trocar Cannulae is available with smooth or threaded sleeve in sizes 5-12mm inner diameter and 75– 100mm length. Cannulae are equipped with a sealing system for maintenance of pneumoperitoneum during insertion and withdrawal of instruments and with a luer stopcock port for insufflation and desufflation of the operative cavity.

Trocar Obturator is available in bladed configuration, sized 5-12 mm. Bladed obturators are equipped with a safety shield designed to expose the blade during insertion but to retract over the tip once the operative cavity has been penetrated, so as to reduce the risk for vascular or visceral injury.

Indications for Use:

Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures including thoracic, gynecologic laparoscopy and other abdominal procedures.

Technological characteristics:

The design, materials, and intended use of Reprocessed Trocars are identical to the predicate devices. The mechanism of action of Reprocessed Trocars is identical to the predicate devices

in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions reprocessing of Trocars includes removal of adherent visible soil and decontamination. Each individual Trocar is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Trocars. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Trocars perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Trocars) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascent Healthcare Solutions
% Ms. Katie Bray
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, Arizona 85044

OCT 2 ˇ 2007

Re: K070059
Trade/Device Name: Reprocessed Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: August 27, 2007
Received: August 29, 2007

Dear Ms. Bray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Devices:

OEM	Model Number	Device	Diameter	Length	Cannula
Ethicon	D5LT	Bladed Trocar, 5mm diameter, 100mm length, Stability sleeve	5mm	100mm	Stability
	D5ST	Bladed Trocar, 5mm diameter, 75mm length, Stability sleeve	5mm	75mm	
	D11LT	Bladed Trocar, 11mm diameter, 100mm length, Stability sleeve	11mm	100mm	
	D12LT	Bladed Trocar, 12mm diameter, 100mm length, Stability sleeve	12mm	100mm	

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SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: Reprocessed Trocars

Indications For Use: Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures including thoracic, gynecologic laparoscopy and other abdominal procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070059